

camera lens. The center of the light pipe should be in the center of the LED lamp and oriented with its long dimension along the long dimension of the camera. The cut out for the lens and the cut out for the light pipe will leave a fairly thin wall between the two cut outs. Placing a thin wall between the light pipe and the lens prevent the lens from being affected by light coming directly from the illumination source. In addition, it has been observed that the color of the body of the smartphone can affect illumination and the results obtained from an assay. For instance, it was observed that light from a white iPhone flash diffuses through the plastic case more than the light from a black iPhone flash. This confounding factor can, for example, be addressed by an algorithm correction or by placing a gasket or physical barrier around the flash to limit and control light diffusion.

**[0107]** The present invention may be embodied in other specific forms without departing from its spirit or essential characteristics. The described embodiments are to be considered in all respects only as illustrative and not restrictive. The scope of the invention is, therefore, indicated by the appended claims rather than by the foregoing description. All changes which come within the meaning and range of equivalency of the claims are to be embraced within their scope.

What is claimed is:

1. A diagnostic test system, comprising:
  - a lateral-flow chromatographic assay cassette that includes: a capture ligand capable of capturing and localizing at least one analyte of interest in a sample on an analysis surface of the lateral-flow chromatographic assay cassette, at least one reporter for visualizing the interaction of the analyte of interest and the capture ligand, and means for providing an at least a two-point calibration curve for quantification of the at least one analyte of interest;
  - a testing device that includes data collection and data analysis capabilities, the testing device including:
    - a testing apparatus configured to interface with the lateral-flow chromatographic assay cassette and position the lateral-flow chromatographic assay cassette in proximity to a light source;
    - the light source being capable of transmitting at least one wavelength of light configured to yield a detectable signal from the at least one reporter; and
    - a detector is positioned to capture the detectable signal from the at least one reporter; and
  - an interpretive algorithm stored in a computer readable format and electronically coupled to the testing device, wherein the interpretive algorithm is configured to (i) calculate a calibration curve and then (ii) convert the detectable signal from the at least one reporter to a numerical value related to the presence or amount of the at least one analyte present in a sample.
2. The diagnostic test system of claim 1, wherein the means includes a lateral-flow chromatographic assay cassette that includes at least a first calibration standard and a second calibration standard configured to provide at least a two-point calibration curve.
3. The diagnostic test system of claim 1, wherein the means includes a lateral-flow chromatographic assay cassette that includes a test strip and a separate calibration strip cassette, wherein the calibration strip includes a capture ligand configured to capture a known amount of the analyte of interest.
4. The diagnostic test system of claim 1, wherein the testing apparatus is physically coupled to the testing device.

5. The diagnostic test system of claim 4, wherein the testing apparatus includes at least one indexing feature configured to align the testing apparatus with the testing device.

6. The diagnostic test system of claim 4, wherein the testing apparatus includes one or more seals to create a light-tight environment between the testing device and the testing apparatus and between the testing apparatus and the lateral-flow chromatographic assay cassette.

7. The diagnostic test system of claim 1, wherein the testing device is selected from the group consisting of a digital camera device, a cellular phone, a smart phone, and a tablet or laptop or desktop computer.

8. The diagnostic test system of claim 1, wherein the light source is at least one of a camera flash, an autofocus illuminator, ambient light, sunlight, an LED light, an incandescent lamp, or a gas-discharge lamp.

9. The diagnostic test system of claim 8, wherein at least one focusing lens is interposed between the light source, the detector, and the analysis surface of the lateral-flow chromatographic assay cassette.

10. The diagnostic test system of claim 8, wherein at least one wavelength filter is interposed between the light source and the analysis surface of the lateral-flow chromatographic assay cassette.

11. The diagnostic test system of claim 8, wherein at least one light conducting fiber is interposed between the light source and the analysis surface of the lateral-flow chromatographic assay cassette.

12. The diagnostic test system of claim 1, wherein the at least one reporter includes at least one of colored beads, colloidal gold, colloidal silver, dyes, fluorescent dyes, an electrochemical detector, a conductivity detector, or quantum dots.

13. The diagnostic test system of claim 1, wherein the detectable signal includes at least one of emission, color intensity, reflectance, diffuse scattering, elastic light scattering, transmission, fluorescence, surface plasmon detection, Rayleigh scattering, electrochemical detection, conductivity, or absorbance.

14. The diagnostic test system of claim 1, the lateral-flow chromatographic assay cassette further including a tracking feature readable by the at least one of the testing device or the testing apparatus, wherein the tracking feature provides values calculating the calibration curve.

15. The diagnostic test system of claim 1, the lateral-flow chromatographic assay cassette further including a first mechanical interlock feature configured to interlock with a corresponding second mechanical interlock feature on the testing apparatus.

16. The diagnostic test system of claim 15, wherein the first and second mechanical interlock features are configured to align the lateral-flow chromatographic assay cassette relative to the testing apparatus, the light source, and the detector.

17. The diagnostic test system of claim 15, wherein the first and second mechanical interlock features are configured to disable the diagnostic test system if the first and second mechanical interlock features do not align when the lateral-flow chromatographic assay cassette is inserted into the testing apparatus.

18. The diagnostic test system of claim 1, the testing apparatus further including a target device capable of being illuminated by the light source and viewable by the detector, wherein the target device is configured for normalizing and/or calibrating the light source and the detector.